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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,271	01/22/2001	Gil H. Choi	PB340P2C3	9691

22195 7590 06/07/2002

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	**PAPER NUMBER**
1645	4

DATE MAILED: 06/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/765,271	Applicant(s) Choi et al
	Examiner Patricia A. Duffy	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-21* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Prior to setting forth the restriction requirement, it is noted out that the claims recite improper Markush Groups. M.P.E.P. 803.02 states that: Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, *unless the subject matter in a claim lacks unity of invention* [emphasis added], *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility." In the instant case, the claims drawn to different nucleic acids encoding separate and distinct polypeptides/epitopes that differ in structure and origin to such an extent that non-coextensive searches are required, and that the polynucleotide are considered to lack a substantial structural feature disclosed as being essential to the disclosed utility. As such, each of the polynucleotides of Table I are restricted each from the other. Applicants are required to elect a single polynucleotide encoding a single polypeptide, a single polypeptide or a single antibody binding the polypeptide to which examination on the merits will be restricted. This is not to be construed as a species election because the polynucleotide sequences of Table 1, nor the epitopes of Table 2 are proper species of each other for reasons set forth directly above.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9 and 13, drawn to an isolated nucleic acid molecule, isolated nucleic acid molecules encoding a polypeptide, vectors, host cells, methods of producing the polypeptide, classified in class 536, subclass 23.7.

II. Claims 10-12, 16 and 20, drawn to polypeptide, polypeptide antigen, vaccine and kit for detecting *Streptococcus*, classified in class 530, subclass 350.

III. Claims 14-15, drawn to an antibody and hybridoma which produces the antibody, classified in class 435, subclass 325.

IV. Claim 17, drawn to a method of prevention infection, classified in class 424, subclass 900.

V. Claims 18 and 19, drawn to a method of detecting *Streptococcus* under conditions such that hybridization occurs and a method of detecting *Streptococcus* using polymerase chain reaction class 435, subclass 6.

VI. Claim 21, drawn to a method of detecting Streptococcus using antigen - antibody complexes, classified in class 435, subclass 7.1.

3. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid products can be used in methods of making the protein, methods of in vivo expression using vaccine vectors and methods of mutagenesis. Because the product as claimed has multiple methods of use, the product is properly restrict able from the method of making.

4. Inventions II and IV or VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used in a method of making an antibody in vitro, in a method of vaccination or in a method to diagnose infection. Because the product as claimed has multiple methods of use, the product is properly restrict able from the method of making.

5. Inventions I, II and III are related as products. The claims of Group I are drawn to a polynucleotide, those of Group II are drawn to a polypeptide and that of Group III to antibodies. The inventions can be shown to be distinct because they are made by different methods and because they are physically and functionally distinct chemical entities. Further, the nucleic acid is not required to produce either the polypeptide or the antibody because the polypeptide can be made synthetically or purified from nature.

6. Inventions IV, V and VI are related as methods. The methods are distinct each from the other because they have different goals as evidenced by the preamble (detection of infection versus prevention of infection), different method steps (hybridization, binding versus administration), utilize different reagents (polynucleotide versus polypeptides versus antibodies) and have different final outcomes. Consequently, each method is distinct from the other.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

10. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Tuesday-Saturday from 10:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.
June 6, 2002

Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600